IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: WAVE 6 CASES ON ATTACHED EXHIBIT A TO PLAINTIFFS' MOTION	

REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF DR. JOHN R. WAGNER

In further support of their Motion to exclude certain opinions and testimony of Defendants' Urology and Female Pelvic Medicine and Reconstructive Surgery expert, John R. Wagner, M.D., ("Dr. Wagner"), Plaintiffs state as follows.

I. Dr. Wagner failed to apply any objective, reliable standard in offering his warnings opinions, in violation of *Daubert*, and his opinions as the knowledge of other individuals is unreliable testimony as to the state of mind of other individuals.

Plaintiffs do not take issue on this motion with Dr. Wagner's credentials. Rather, Plaintiffs' claim is that Dr. Wagner opinions are entirely subjective, without reference to any objective source or standard. The opposition brief fails to identify any standard or methodology applied by Dr. Wagner, or any standard by which Dr. Wagner's opinions on the warnings can be objectively evaluated. That gap is fatal to Dr. Wagner's warning opinions. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014), this Court precluded an expert's warning opinions because the expert applied no standard at all to support his opinions. This Court wrote: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is

based on mere speculation and personal belief." *Id.* at *32. The same applies to Dr. Wagner, who has conducted no scientifically reliable inquiry into what physicians actually knew about the risk of the pelvic mesh devices.

The Defendants' position is that Dr. Wagner should be permitted to testify concerning the knowledge of the medical community concerning the risks of the pelvic mesh devices. (Def. Mem. at 2-3). This court has repeatedly and consistently held that experts cannot testify as to a manufacturer's knowledge or state of mind when issuing rulings on expert testimony. *See, e.g.*, *In re C.R. Card, Inc.*, 948 F. Supp. 2d 589, 611, 620 (S.D. W. Va. 2013). Moreover, this court has also made clear that an expert "cannot testify as to what someone else did or did not know" because this opinion "reaches a conclusion as to the mental state of the plaintiff's implanting surgeon." *Guinn v. Ethicon, Inc.*, No. 2:12-cv-01121 (Dkt. No. 119 at 5) (S.D. W. Va. Feb. 3, 2017) (excluding opinion that the implanting surgeon was unaware of the risks of vaginal mesh implants), attached as Ex. A; *see also Wiltgen v. Ethicon, Inc.*, No. 2:12- cv-01216 (Dkt. 142 at 4) (S.D. W. Va. Feb. 3, 2017) (same), attached as Ex. B. This Court should follow the same logic here with regard to Dr. Wagner. If an expert cannot testify as to the mental state of a specific physician, then surely Dr. Wagner cannot testify as to the metal state of "physicians in the medical community" regarding the risks of the pelvic mesh products. This is particularly true when Dr. Wagner has no basis or foundation for that opinion, other than his personal convictions.

Defendants failed to address Dr. Wagner's testimony that he does not feel qualified to determine the adequacy of the pelvic mesh IFUs and feels that that question is better left to regulators.[1] The clear inference to be drawn from Dr. Wagner's opinion—i.e., that the risks of the pelvic mesh devices were well known in the medical community—is that the IFU were, in

[1] *See* Pl. Mem. at 4-5, citing Ex. G., Wagner 9/25/2017 Dep. at 102:11-24 .

fact, adequate. This effort to justify the expert's deficient methodology should not be allowed. Defendants are essentially asking the court to allow Dr. Wagner to opine about the adequacy of the pelvic mesh IFUs without applying any objective standard, and without any foundation for the opinion. The only "foundation" is the witness's personal beliefs about what other doctors already know, or should know. Dr. Wagner has performed no reliable or verifiable study or analysis of what surgeons did or did not know, as would be necessary to support the opinion that a particular warning was unnecessary. Dr. Wagner admitted that he lacked any foundation to opine as to what surgeons generally knew about the risks of pelvic surgery with mesh:

> Q. Well, my question is have you ever done any kind of study or analysis to determine what percentage of pelvic floor surgeons did in fact know of all of these risks,[2] in say, 2012?
>
> A. Again, that's such a funny question. No, I've never done a study that looks at whether the pelvic surgeons learned what they were supposed to learn about pelvic floor surgery. It does not make sense, that question.

(Ex. G. to Pl.'s Mot., at 84:11-22). Thus, Dr. Wagner is opining as to what, in his mind, physicians should have learned about pelvic floor surgery. This is an inadmissible *ipse dixit* opinion. *See, e.g.*, *GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011).

In addition, Dr. Wagner's testimony becomes unreliable when he makes the leap to assume that all physicians have been trained in the manner which he believes they should be trained, and have learned what he believes they should have learned, without any reliable basis or methodology in arriving at these conclusions. We simply have Dr. Wagner's say so, which is insufficient under *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999)

[2] The risks in question are those cited on Page 34 of Dr. Wagner's Prolift report and are: incontinence, urinary retention, voiding dysfunction, urinary tract infection, overactive bladder symptoms (include frequency, urgency and urge incontinence), as well as tissue and organ damage, nerve damage, hematoma, wound complications, excessive scarring, vaginal pain, pelvic pain and pain with sexual intercourse. *See* Ex. G to Pl's motion at 82:6-13; *See also* Ex. F. to Pl's motion at 34.

(stating that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

Dr. Wagner's subjective, unsupported opinions regarding the knowledge of the medical community should be excluded under *Daubert.* They should also be disallowed under this court's previous rulings that an expert cannot testify as to another doctor's knowledge or state of mind. Moreover, allowing Dr. Wagner's opinion that a "well trained" surgeon would know or should know of these risks would create FRE 401 and 403 issues in these cases. The natural conclusion the jury will draw from this testimony is that the warning provided by Defendants was adequate, or that the implanting physician fell below the standard of care if he did not know these risks, despite the expert applying no objective standard to arrive at that conclusion. Thus, Dr. Wagner's warning opinions should be precluded.

II. Dr. Wagner is not qualified to give opinions on the design of the mesh products, and he has relied on no objective standard in reaching his conclusions regarding the safety and efficacy of the mesh products.

Dr. Wagner's is admittedly not an expert in design, and Defendants appear to concede that he is "a design expert only from a clinical perspective based in his clinical experience and review of the literature." (Def. Mem. at 8). Thus, Defendants essentially admit that Dr. Wagner is not qualified to testify about the design features of the device, including but not limited to whether or not the mesh is too heavy, too stiff, degrades, has pores that are too small, ropes, curls, frays and loses particles, is cytotoxic as well as the clinical consequences alternative of mesh designs which do not have those characteristics. Dr. Wagner's use of mesh products, and his qualifications as a Pelvic Reconstructive Surgeon do not, by themselves, uniquely qualify him to opine regarding the safety and efficacy of a medical device. Defendants claim that the basis of Dr. Wagner's design opinions is his "clinical experience and review of the literature."

(Def. Mem. at 8). A review of the literature does not provide sufficient basis for Dr. Wagner to offer a reliable design opinion unless he can identify an appropriate standard that he applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

In regards to Dr. Wagner's opinion that the mesh in the pelvic mesh products is lightweight, Defendants do not address Plaintiffs' argument that Dr. Wagner has applied no objective, numerical standard for his opinions that the mesh is lightweight. Further, Defendants do not address the fact that objective, numerical standards defining mesh as lightweight exist,[3] or the fact that Dr. Wagner has admitted he is unaware of such objective, numerical standards, and therefore has not considered them or any other objective standard when issuing an opinion that a particular mesh is considered lightweight.[4] Defendants then claim that the term "lightweight" is not a scientific term, and then contradict this argument by citing an alternative piece of scientific literature for the proposition that the mesh in Ethicon's devices is "light." (Def Mem. at 9, citing Ex. D to Def. Mem.). Defendants ignore the fact that the single piece of literature they cite still does not contain an objective, numerical standard for its conclusion that the mesh is "light,"[5] and therefore it suffers from the same shortcomings as Dr. Wagner's analysis. Simply finding a piece of medical literature and parroting its conclusions without performing any analysis does

[3] *See* Ex. C. attached hereto Cobb., et al., The Argument for Lightweight Polypropylene Mesh in Hernia Repair, at 64, defining lightweight meshes as having a weight of 35 g/m of polypropylene and have pores in the range of 3 to 4 mm.
[4] *See* Ex. G to Pl's motion 46:19-47:3
[5] Moreover, the Jones study cited in Defendant's memorandum at page 9 and attached as Exhibit E does not define Ethicon's Gynemesh PS as "lightweight", it simply state it is "lighter weight" in comparison to its other meshes used in abdominal hernia repairs. See Def. Ex. E at 848.

not meet the standard required under *Daubert.* According to Dr. Wagner's standards, any mesh can be considered lightweight or large pore as long as he can find a single piece of literature stating that the mesh has those properties. Nowhere does Dr. Wagner or Ethicon identify any objective standard that he applied, such that his opinions on the weight and pore size of the mesh could be objectively evaluated. Moreover, as discussed in Section III of Plaintiffs' Memorandum, Dr. Wagner has not properly disclosed the basis for his opinions, including what materials he actually reviewed and relied upon in forming his opinions. As such, he should be precluded from giving any opinions related to the design of mesh products, including whether the mesh in question is heavyweight or small pore.

III. Dr. Wagner should be precluded from giving any opinions on the safety of the Prolift product, as his opinions are not based on objective standards, and he has not disclosed the basis for his opinions.

Defendants' response brief ignores that, according to Dr. Wagner's standards, no device can ever be unsafe or ineffective. Dr. Wagner admitted that he could potentially find that a pelvic mesh device which eroded in 100 percent of cases might still be safe and effective.[6] He has admitted that he cannot state an objective standard for his declaration that a pelvic mesh device is not safe or not effective.[7] Nowhere does Dr. Wagner or Ethicon identify any objective standard applied by Dr. Wager, or by which Dr. Wagner's opinions on safety and efficacy can be tested or objectively evaluated.

Moreover, Defendants claim that Plaintiffs are suggesting that Dr. Wagner's opinions are somehow not reliable because he may not have closely reviewed every single work referenced on his reliance list. (Def. Mem. at 16). However, his failure to review materials is only part of the problem. Plaintiffs also take issue with Dr. Wagner's, and Ethicon's failure to provide an

[6] Pl's motion Ex. G. at 108:6-14; 111:24-112:18
[7] *Id.*

accurate list of the facts and data he did actually consider in forming his opinions in this case. Thus, Plaintiffs have insufficient information to examine the basis of his opinions, let alone address their reliability. (*See* Pl. Mem. at 10). Defendants attempt to ignore this violation of the rules and skirt the issue by stating that Dr. Wagner cites "numerous articles that support his opinions" and has reviewed a "vast amount of literature."[8] But they ignore the fact that Ethicon and Dr. Wagner have failed to do what is required by the Federal Rules—provide a list of the materials that the expert actually reviewed and relied upon in forming his opinions. The rule do not request a list of materials that were made available to him by defense counsel, from their "library." Nowhere in their memorandum do defendants state or argue that Dr. Wagner has actually complied with the requirements of F.R Civ. P 26(a)(2)(B)(ii). As such, Dr. Wagner should be precluded from giving any opinions related to the adequacy of the design, safety, and efficacy of the Prolift, as provided in F.R Civ. P 37(c)(1)—and also because Dr. Wagner has failed to apply an objective, reliable standard for these opinions under *Daubert*.

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Respectfully submitted,

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[8] Def. Memorandum at 16.

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CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Thomas P. Cartmell